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EXAMINER	
MATTER, KRISTEN CLARETTE	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
08/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/502,405	BONNEY ET AL.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 7/25/2002. It is noted, however, that applicant has not filed a certified copy of the 0217199.9 application as required by 35 U.S.C. 119(b).

Receipt is acknowledged of papers submitted for the 0201677.2 application filed on 1/25/02 in the United Kingdom under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings are objected to because exploded views (such as seen in Figures 9b, 10c, 11a, 11b, and 12b) must include a connection means (i.e., a bracket or dashed line) showing how the parts are connected and/or indicating that the elements are all part of the same figure as opposed to separate figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11, 12, 14, 31, 32, 34, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Goede et al. (US 7,234,464).

Regarding claim 1, Goede et al. discloses an inhaler comprising first and second medicament containers (2, 3) and first and second release means (5; see column 6, lines 65-68). The two medicaments are kept separate from each other until the point of release and the first medicament contains salmeterol and the second medicament contains fluticasone (see column 4, lines 50-60).

Regarding claims 11, 12, and 14, Goede et al. discloses that each container has storage from multiple doses that are metered out to provide a dose quantity that is made available for inhalation (see column 6, line 65-column 7, line 3).

Regarding claim 31, the first and second release means are physically coupled by the chamber (4).

Regarding claims 32 and 33, the containers are sized and shaped to release either the sane or different dose portions (i.e., the containers are the same dimensions, but dosage can be altered by the metering means).

Regarding claims 34 and 35, Goede et al. discloses that the containers are inserted together into an inhaler device (and can therefor be replaced; see column 6, lines 50-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-7, 20-22 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goede et al.

Regarding claims 2-6 and 20, Goede et al. is silent as to the claimed combination of specific components or a pure drug. However, absent a critical teaching and/or a showing of

unexpected results from using the combination of components or a pure drug, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used any combination of well known and commonly used components in the device of Goede et al. because it would have provided the means for storing pharmaceuticals commonly used to treat respiratory disorders whose individual active substances are incompatible with each other as regarding storage life (column 4, lines 45-50). In addition, it appears as though the device of Goede et al. would perform equally well with any of the claimed combinations of components for treating a respiratory disorder by inhalation therapy.

Regarding claim 7, although Goede et al. discloses multiple powder doses within the containers, absent a critical teaching and/or a showing of having a unit dose container pack, examiner contends it is an obvious design consideration to one of ordinary skill in the art to have single use inhalers with a unit dose of medicine stored in a container as opposed to multiple doses in order to avoid contamination and cleaning problems that come with repeated use of a single device for multiple doses. In addition, it appears as though the device of Goede et al. would perform equally well if the containers held a unit dose and opposed to multiple doses.

Regarding claims 21 and 22, Goede et al. is silent as to the claimed excipient. However, absent a critical teaching and/or a showing of unexpected results from using a claimed excipient, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used one of the claimed excipients in the device of Goede et al. in order to dilute the drug or add a desired consistency.

Regarding claim 37, Goede et al. discloses the claimed structure of the dispenser. The method steps would have been obvious to one of ordinary skill in the art because they would have directly resulted from use of the device of Goede et al.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goede et al. as applied to claims 1, 11, 12, and 14 above, and further in view of Ivri et al. (US 6, 640, 804). Goede et al. is silent as to the metering cavity being movable from a first to second position for the delivery of the medicament. However, Ivri et al. discloses a metering chamber for an inhaler that moved from a first position (Figure 15) in which medicament from the reservoir fills the metering cup to a second position (Figure 16) in which the dose is made available to the patient for inhalation. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have replaced the container and/or metering means of Goede et al. with the container and/or metering means of Ivri et al. in order to precisely meter out a desired dosage of medicament for each container. Furthermore, it appears as though the device of Goede et al. would perform equally well if a liquid medicament were used and/or if the movable metering chamber of Ivri et al. were used in place of the sliding metering means.

Claims 1-10, 11, 14-22, and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casper et al. (US 2007/0181124) in view of Goede et al.

Regarding claims 1-6 and 20, Casper et al. discloses a an inhaler comprising first and second medicament containers containing different medicaments (abstract) and first and second release means (piercing member or inhalation channels). Casper et al. is silent as to the specific

claimed medicaments or a pure drug form. However, absent a critical teaching and/or a showing of unexpected results from using the combination of components or a pure drug, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used any combination of well known and commonly used components in the device of Casper et al. because it would have provided the means for storing pharmaceuticals commonly used to treat respiratory disorders whose individual active substances are incompatible with each other as regarding storage life. In addition, it appears as though the device of Casper et al. would perform equally well with any of the claimed combinations of components for treating a respiratory disorder by inhalation therapy.

Regarding claims 7-9 and 14-18, Casper et al. discloses the medicaments in unit dose form or multi-dose form (each medicament can be considered a separate dose or the two together can be considered as a "single dose") as capsules (Figure 1A), blister packs (Figure 4), or carriers (Figure 9A).

Regarding claims 10 and 19, Casper is silent as to how the medicament is applied to the carrier. However, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)(citations omitted).

Regarding claims 21 and 22, Casper et al. discloses powder drugs but is silent as to the claimed excipient. However, absent a critical teaching and/or a showing of unexpected results

from using a claimed excipient, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used one of the claimed excipients in the device of Casper et al. in order to dilute the drug or add a desired consistency.

Regarding claim 31, the first and second release means are physically coupled by the housing or mouthpiece.

Regarding claim 32, the containers of Casper et al. are sized and shaped to deliver equivalent dose portions.

Regarding claim 33, Casper et al. does not disclose that the containers are sized and shaped to deliver or non-equivalent dose portions. However, absent a critical teaching and/or a showing of unexpected results from sizing the containers to deliver or non-equivalent dose portions, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have sized the containers to deliver or non-equivalent dose portions in order to deliver different amounts of each drug during the combination therapy. Furthermore, a mere change in size dose not patentably distinguish over the prior art and it appears as though the device of Casper et al. would perform equally well if the containers were different sizes.

Regarding claim 34, Casper et al. discloses the containers being in reloadable form (i.e., blister packs and capsules are well known as being reloadable).

Regarding claims 35 and 36, the containers of Casper et al. can Be considered to be a single refill cassette or separate refills (i.e., blister pack fused or unfused and/or capsules).

Regarding claim 37, Casper et al. discloses the claimed structure of the dispenser. The method steps would have been obvious to one of ordinary skill in the art because they would have directly resulted from use of the device of Casper et al.

Claims 1-7, 11, 12, 14, 20, 31-34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trueba (US 6,684,880) in view of Goede et al.

Regarding claims 1-6 and 20, Trueba discloses an inhaler with first and second medicament containers (50-56) having first and second release means (40-46). Trueba discloses that the containers can contain different medicaments (column 3, lines 1) but is silent as to the claimed combinations of drugs. However, Goede et al. discloses salmeterol and fluticasone as well known and commonly used drugs in combination therapy that need stored separately. Therefore, it would have been obvious to use salmeterol and fluticasone in the device of Trueba as taught by Goede et al. in order to provide a well known and commonly used combination therapy to a patient via inhalation. Furthermore, absent a critical teaching and/or a showing of unexpected results from using the combination of claimed components or a pure drug, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used any combination of well known and commonly used components in the device of Trueba because it would have provided the means for storing pharmaceuticals commonly used to treat respiratory disorders whose individual active substances are incompatible with each other as regarding storage life. In addition, it appears as though the device of Trueba would perform equally well with any of the claimed combinations of components for treating a respiratory disorder by inhalation therapy.

Regarding claims 7, 11, and 14, Trueba discloses that the containers can include a single dose or multiple doses (column 4, lines 35-40).

Regarding claim 12, Trueba discloses that the medicament is metered for each container (column 11, lines 1-3).

Regarding claim 31, the release means are physically coupled by the housing (32).

Regarding claims 32 and 33, the containers are sized and shaped to release either the sane or different dose portions (i.e., the containers are the same dimensions, but dosage can be altered by the input means).

Regarding claim 34 and 36, Trueba discloses that the containers are replaceable (column 4, lines 35-40).

Regarding claim 37, Trueba discloses the claimed structure of the dispenser. The method steps would have been obvious to one of ordinary skill in the art because they would have directly resulted from use of the device of Trueba.

Claims 13 and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trueba and Goede et al. as applied to claims 1-7, 11, 12, 14, 20, 31-34, 36, and 37 above and further in view of Ivri et al.

Regarding claims 13 and 23, to the extent that Trueba is silent as to the metering means moving from a first to second position or comprising a valve, Ivri et al. discloses a valve with a metering chamber for an inhaler that moved from a first position (Figure 15) in which medicament from the reservoir fills the metering cup to a second position (Figure 16) in which the dose is made available to the patient for inhalation. Therefore, it would have been obvious to

one of ordinary skill in the art at the time of the invention to have replaced the container and/or metering means of Trueba with the container and/or metering means of Ivri et al. in order to precisely meter out a desired dosage of medicament for each container. Furthermore, it appears as though the device of Trueba would perform equally well if a liquid medicament were used and/or if the movable metering chamber of Ivri et al. were used in place of the disclosed metering means.

Regarding claim 24, the modified Trueba device is silent as to the metering volume of liquid. However, absent a critical teaching and/or a showing of unexpected results from the metering valve having a volume of 10-100 microliters, examiner contends it is an obvious design consideration to one of ordinary skill in the art to provide the claimed metering volume in the modified Trueba device because these volumes are well known and commonly used in the treatment of respiratory disorders by inhalation therapy. Furthermore, it appears as though the modified Trueba device would perform equally well with the claimed volume.

Regarding claims 25-30, Trueba is silent as to the claimed aerosol components. However, absent a critical teaching and/or a showing of unexpected results from using the claimed aerosol components, examiner contends it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to have used any of the claimed components in the modified Trueba device because the components are well known and commonly used to treat respiratory disorders by inhalation therapy. Furthermore, it appears as though the modified Trueba device would perform equally well with any of the claimed components.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 and 37 of copending Application No. 10/522,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of at least one actuation indicator as in the copending claim 1). In the instant claim 1, the structural elements are included in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-37 do not differ from the scope of the copending claims 1-35 and 37.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 and 38 of copending Application No. 10/522,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the electric control system as in the copending claim 1). In the instant claim 1, the structural elements are included in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-37 do not differ from the scope of the copending claims 1-36 and 38.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-22 of copending Application No. 10/523,121. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the

mechanically coupled release means as in the copending claim 1). In the instant claim 1, the structural elements are included in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-37 do not differ from the scope of the copending claims 1-7 and 9-22.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hickey et al. is cited to show another inhaler that delivers two separate medicaments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771